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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,868	07/17/2000	Thomas J. Shaw	75329 77432	8293

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EXAMINER	
MACNEILL, ELIZABETH	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/617,868	SHAW, THOMAS J.	
	Examiner	Art Unit	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34,36-42,44-50,52,54,55,58-94 and 96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-34,36-42,44-50,52,54,55, 58-94 and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendments submitted 2 November 2006. The previous indications of allowable subject matter are withdrawn. A new rejection follows.

Claim Objections

1. Claim 29 objected to because of the following informalities: there is a period after the 6th paragraph of the claim. This must be changed to either a semi-colon or comma. Appropriate correction is required.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 29-34, 36-42, 44-50, 52, 54,55 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by TSAO (US 5,084,018).

Regarding claims 29,37,45,54, and 96, Tsao teaches a syringe assembly having a retractable needle and designed for one-time use, comprising: a hollow syringe body comprising a barrel (12) having a front end portion containing a retraction mechanism (38) having a retractable needle (30), a needle holder having an inner head (34) and a continuous retaining member (26) configured for operation by forward movement of a plunger (50), and a back end portion having an opening (above 11); the continuous retaining member surrounding the inner head of the needle holder and having a surface mating (26) with a facing surface of the hollow syringe body, thereby making a seal for a

variable fluid chamber in the barrel; a plunger having a front end portion (54) comprising a head (56), an outer wall surface on the plunger front end portion having a plunger seal (58) element fixed on the outer wall surface, and a back end portion with an end cap (59) having an outer periphery; the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and the retraction mechanism being released for retraction of the retractable needle when the plunger is moved forward to release the continuous retaining member, without moving the plunger seal element longitudinally along the outer wall surface by contact between the plunger seal element and the continuous retaining member, the outer periphery of the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction. See the progression from Fig 1 to Fig 4.

Regarding claims 30, 39, and 47 a structure (24) mounted in the front end portion of the barrel prevents forward motion of the retractable needle during retraction of the needle to prevent pain when the needle is retracted from a patient.

Regarding claims 31,41,42, and 49 the plunger carries a tip (56) which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

Regarding claims 32,38, and 46, the continuous retaining member is a separable part of the retraction mechanism which acts as a fluid seal for a variable chamber in the barrel behind the separable part. See Fig 1

Regarding claims 33 and 48the continuous retaining member is separable from the inner head of the needle holder when retraction is initiated by pushing on the plunger. See Fig 3

Regarding claims 34, 40, 50, and 55 the continuous retaining member is separated from the inner head of the needle holder by means of force applied by said tip to said continuous retaining member when retraction is initiated by pushing on said plunger. See Fig 3

Regarding claims 36, 44, and 52, the outer periphery of the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, whereby the plunger cannot be grasped after retraction. See Fig 4.

3. Claims 58-94 are rejected under 35 U.S.C. 102(b) as being anticipated by PRESSLY et al (US 5,211,629).

Regarding claims 58 and 81, Pressly et al teaches a syringe having a hollow body (5) with first (9, distal) and second (proximal, unlabeled) open ends and an inside wall of varying inside diameter extending between the first and second open ends (Fig 1), a needle retraction mechanism (13) insertable into the body through the second open end, a plunger (7) having a forwardly extending plunger head (43) insertable into the body through the second open end behind the needle retraction mechanism, and a needle (3) extending forwardly of the first open end, wherein: the body comprises a nose (9, walls unlabeled at distal-most end of the syringe body) adjacent to the first

open end, a barrel adjacent to the second open end, and a transition zone between the nose and barrel; the needle retraction mechanism is grounded inside the nose and comprises an elongated needle holder and a spring (21); the elongated needle holder further comprises a needle holding portion (13) secured in fixed relation to the needle, a reduced diameter portion at one end of the needle holding portion, the reduced diameter portion extending forwardly through the first open end (the reduced diameter portion, the distal-most section of element 13, is seen extending between the walls 23 of the nose portion of the first open end in Fig 1); a head (top, proximal end of 13) at another end of the needle holding portion opposite the reduced diameter portion; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger (not labeled, taken as lumen of the needle/needle holding portion); and a retainer member (11) having a first annular surface (engaging 17) slidably engaging the needle holder head and a second annular surface (engaging 9) slidably engaging the inside wall of the body opposite the needle holder head; the spring is confined prior to retraction inside the nose in an annulus defined by the needle holding portion and a portion of the inside wall opposite the needle holding portion (Fig 1); the plunger head has a tip (43) aligned to abut against the retainer member and slide the retainer member longitudinally out of engagement with the needle holder head during retraction (Fig 2); and the plunger comprises a retraction cavity (41) into which part of the retraction mechanism is received during retraction to withdraw the needle into the body through the first open end.

Regarding claims 59 and 82, the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose (Fig 1).

Regarding claim 60, further comprising an annular shoulder (on element 13, (17)) between the needle holding portion and the reduced diameter portion, the annular shoulder abutting against the inside wall proximal to the first open end to ground the elongated needle holder inside the nose.

Regarding claims 61 and 94, the tip of the plunger head defines an opening into the retraction cavity (Fig 2)

Regarding claim 62, a resilient dislodgeable stopper (43) is positioned in the opening into the retraction cavity.

Regarding claim 63, a front portion of the dislodgeable stopper extends forwardly of the tip (Fig 1)

Regarding claim 64, the plunger head further comprises a slidable seal (43) contacting the inside wall of the barrel.

Regarding claim 65, the seal is mounted in a fixed axial position on the plunger (Fig 1)

Regarding claim 66, the plunger further comprises a rear end portion (45) opposite the plunger head, and a thumb cap at the rear end portion

Regarding claim 67, the thumb cap has an opening (Fig 10A).

Regarding claim 68, a closure installed in the opening and the retraction cavity is vented (Fig 10A).

Regarding claims 69 and 83, the barrel comprises a collar (47) adjacent to the second open end, and the thumb cap fits closely inside the collar when the plunger is depressed during retraction (Fig 2).

Regarding claims 70 and 93, the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel (Fig 2)

Regarding claims 71 and 88, the syringe is made of a one-piece barrel.

Regarding claims 72 and 84, the retainer member is positioned at the most constricted portion of the transition zone where the nose begins (Fig 1).

Regarding claims 73 and 85, the retainer member engages the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the spring when the spring is compressed (Fig 1).

Regarding claims 74 and, the nose comprises an annular space between the inside wall and the spring into which the retainer member is forced upon separation from the needle holder head by the plunger tip during retraction (Fig 2).

Regarding claims 75,86 and 87, the needle is inserted into the reduced diameter portion of the elongated needle holder extending forwardly of the body and is attached to the elongated needle holder (Fig 1).

Regarding claims 76 and 88, the inside wall of the nose functions as a spring guide during compression of the spring (Fig 1).

Regarding claims 77 and 90, the retainer member has an outside mating surface (against wall 9) making a seal with the inside wall.

Regarding claims 78 and 91, at least a portion of the retraction mechanism is received into the retraction cavity during retraction (Fig 2, cavity 41).

Regarding claim 79, the retraction mechanism is releasable by forward movement of the plunger to disengage the retainer member from the needle holder head without contact between the plunger seal element and the retainer member (Fig 1 to Fig 2).

Regarding claims 80 and 92, the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction (Fig 1).

Response to Arguments

4. Applicant's arguments with respect to claims 29-34, 36-42, 44-50,52, 54,55, 58-94 and 96 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

11/9/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER